

Dockets Management Branch (HFA-305)  
Docket No. OON-0506  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

March 22, 2000

To whom it may concern:

The Executive Council of the Organization of Teratology Information Services (OTIS) would like to comment on **the Dietary Supplement Health and Education Act of 1994 (DSHEA), specifically regarding claims made for dietary supplements concerning the effect of the product on the structure/function of the body.** Our concern is that the proposed rule which classifies “ordinary morning sickness” and “leg edema” associated with pregnancy as “common conditions” that are not “diseases” will permit dietary supplement manufacturers to promote products as treatments for these conditions **without first proving that the products are safe and effective in pregnancy.**

This FDA ruling **sets a dangerous precedent for two reasons:**

1. **Classifying “morning sickness” as a “common condition associated with natural states or processes” may be accurate in some cases. However, for those women who suffer from severe and protracted nausea and vomiting during pregnancy (NVP), this classification trivializes a progressively serious disorder and may deter women from seeking necessary medical treatment. Although NVP spontaneously resolves in many women, others continue to have persistent, intractable NVP, which can compromise the nutritional status of both the mother and the developing child. This condition, known as hyperemesis gravidarum, is a serious disorder that can lead to weight loss, dehydration, electrolyte disturbances, and significant morbidity and mortality in cases improperly treated. Because of the potential maternal and fetal complications, hyperemesis gravidarum requires prompt and aggressive treatment. Treatment with medications known to alleviate nausea and vomiting prevents hospitalization in many cases and decreases morbidity. In controlled trials, many of these antiemetics have been shown to be safe and effective to use during pregnancy. Although NVP occurs in 50-70% of all pregnant women, classifying it as a “natural” pregnancy-related condition can be misleading and may encourage some women to use “natural” products which have not been tested for efficacy or for teratogenicity. While there are anecdotal reports of the efficacy of dietary supplements for women with NVP, controlled trials have not been conducted.**

2. Teratology Information Specialists counsel tens of thousands of pregnant women each year on the potential teratogenicity of drugs, medications and other products used to treat maternal diseases, as well as “normal” conditions of pregnancy. In our experience, it is a common misunderstanding among pregnant women that so-called “natural” herbal or dietary supplement products are not medications. Consequently, a great deal of our counseling time is spent educating pregnant women, their partners and health care providers about what really constitutes an “exposure” and therefore may have the potential to interfere with normal development of the fetus. **OTIS’ approach to risk assessment is that, in the absence of adequate human data evaluating the use of any agent during pregnancy (including dietary supplements), we cannot speculate on the safety of these exposures, regardless of whether the agent is used to treat a disease or a normal condition of pregnancy.**

Allowing dietary supplement manufacturers to promote the use of their products to treat certain conditions of pregnancy is likely to be interpreted as a reassurance of safety. If such products have not undergone the scientific scrutiny necessary to support claims of safety and efficacy, pregnant women and their developing babies should be so informed. Any promotional claims that suggest that dietary supplements would not cause maternal or fetal harm are not based on rigorous scientific investigation.

**In the opinion of OTIS, formal scientific investigation of efficacy and teratogenicity of products used during pregnancy is fundamental.** Thank you for considering our position on this matter.

Sincerely,

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